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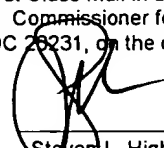
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August 23, 2001

FILE: OST5:003USD2

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date below:	
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Commissioner for Patents  
Washington, DC 20231

RE: SN 09/879,445 "SCREENING ASSAY FOR THE IDENTIFICATION OF AGENTS WHICH ALTER EXPRESSION OF PTH-rP" - Gregory R. Mundy and Wolfgang E. Gallwitz


Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10105044/SLH.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

  
Steven L. Highlander  
Reg. No. 37,642

SLH/cmb  
Encl: as noted



#3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Gregory R. Mundy  
Wolfgang E. Gallwitz

Serial No.: 09/879,445

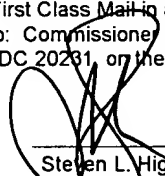
Filed: June 11, 2001

For: SCREENING ASSAY FOR THE  
IDENTIFICATION OF AGENTS WHICH  
ALTER EXPRESSION OF PTH-rP

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: OSTs:003USD2/SLH

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Date	Steven L. Highlander

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

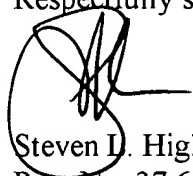
In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10105044/SLH.

This application is a divisional application of Serial No. 09/283,675, filed April 1, 1999 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/283,675.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Steven D. Highlander  
Reg. No. 37,642  
Attorney for Applicants

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Date: August 23, 2001

**Form PTO-1449** (modified)Atty. Docket No.  
OSTS:003USD2/SLHSerial No.  
09/879,445

List of Patents and Publications for Applicant's

**INFORMATION DISCLOSURE STATEMENT**Applicant  
Gregory R. Mundy  
Wolfgang E. GallwitzFiling Date:  
June 11, 2001Group:  
Unknown

(Use several sheets if necessary)

U.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1**U.S. Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date if App.
	A1						

**Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 96/22790	8/1/96	PCT			

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C1	Alam and Cook, "Reporter Genes: Application to the Study of Mammalian Gene Transcription," <i>Anal Biochem</i> , 188:245-254, 1990.
	C2	Bouizar Z, Spyrtos F, Deytieu S, de Vernejoul MC, Jullienne A. Polymerase chain reaction analysis of parathyroid hormone-related protein. <i>Cancer Res</i> 53: 5076-5078, 1993
	C3	Bundred NJ, Walker RA, Ratcliffe WA, Warwick J, Morrison JM, Ratcliffe JG. Parathyroid hormone related protein and skeletal morbidity in breast cancer. <i>Eur J Cancer</i> 28: 690-692, 1992.
	C4	Burtis WJ, Wu T, Bunch C, Wysolmerski JJ, Insogna KL, Weir EC, Broadus AE, Stewart AF. Identification of a novel 17,000 dalton parathyroid hormone-like adenylate cyclase-stimulating protein from a tumor associated with humoral hypercalcemia of malignancy. <i>J Biol Chem</i> 262: 7151-7156, 1987.
	C5	Casey <i>et al.</i> , "Regulation of Parathyroid Hormone-Related Protein Gene Expression in Human Endometrial Stromal Cells in Culture," <i>J Clin Endocrinol Metab</i> , 77(1):188-194, 1993.
	C6	Guisse TA, Yoneda T, Yates AJ, Mundy GR. The combined effect of tumor-produced parathyroid hormone-related protein and transforming growth factor $\alpha$ enhance hypercalcemia <i>in vivo</i> and bone resorption. <i>J Clin Endocrinol. Metab.</i> 77:40-45, 1993.

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Examiner:

Date Considered:

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**Information Disclosure Statement — PTO-1449 (Modified)**

A: 125525(25065892\_1)



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OSTS:003USD2/SLHSerial No.  
09/879,445

List of Patents and Publications for Applicant's

**INFORMATION DISCLOSURE STATEMENT**

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Applicant  
Gregory R. Mundy  
Wolfgang E. GallwitzFiling Date:  
June 11, 2001Group:  
UnknownU.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C7	Karaplis AC, Luz A, Glowacki J, Bronson RT, Tybulewicz VL, Kronenberg HM, Mulligan RC. Lethal skeletal dysplasia from targeted disruption of the parathyroid hormone-related peptide gene. <i>Genes Dev</i> 8:277-289, 1994.
	C8	Lanske B, Karaplis AC, Lee K, Luz A, Vortkamp A, Pirro A, Karperien M, Defize LHK, Ho C, Mulligan RC, Abou-Samra A, Juppner H, Segre GV, Kronenberg HM. PTH/PTHrP receptor in early development and indian hedgehog-regulated bone growth. <i>Science</i> 273:663-666, 1996.
	C9	Liapis H, Crouch EC, Grosso LE, Kitazawa S, Wick MR. Expression of parathyroid-like protein in normal, proliferative, and neoplastic human breast tissues. <i>Am J Pathol</i> 143: 1169-1178, 1993.
	C10	Moseley JM, Kubota M, Diefenbach-Jagger H, Wettenhall REH, Kemp BE, Suva LJ, Rodda CP, Ebeling PR, Hudson PJ, Zajac JD, Martin TJ. Parathyroid hormone-related protein purified from a human lung cancer cell line. <i>Proc Natl Acad Sci USA</i> 84: 5048-5052, 1987.
	C11	Mundy GR. Malignancy and hypercalcemia. In Calcium Homeostasis - Hypercalcemia and Hypocalcemia. Second Editor, Martin Dunitz, London, 1990.
	C12	Powell GJ, Southby J, Danks JA, Stillwell RG, Hayman JA, Henderson MA, Bennett RC, Martin TJ. Localization of parathyroid hormone-related protein in breast cancer metastases - increased incidence in bone compared with other sites. <i>Cancer Res</i> 51: 3059-3061, 1991.
	C13	Search Report, PCT/US97/14836, dated July 2, 1998.
	C14	Southby J, Kissin MW, Danks JA, Hayman JA, Moseley JM, Henderson MA, Bennett RC, Martin TJ. Immunohistochemical localization of parathyroid hormone-related protein in human breast cancer. <i>Cancer Res</i> 50: 7710-7716, 1990.
	C15	Stewart AF. PTHrP(1-36) as a skeletal anabolic agent for the treatment of osteoporosis. <i>Bone</i> 19:303-306, 1996.
	C16	Strewler GJ, Stem PH, Jacobs JW, Eveloff J, Klein RF, Leung SC, Rosenblatt M, Nissenson RA. Parathyroid hormone-like protein from human renal carcinoma cells: structural and functional homology with parathyroid hormone. <i>J Clin Invest</i> 80: 1803-1807, 1987.

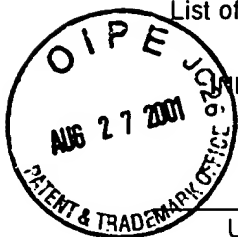
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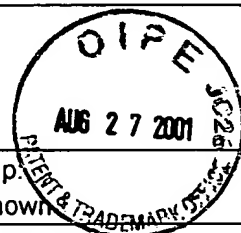
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**Information Disclosure Statement — PTO-1449 (Modified)**

A: 125525(25065892\_1)



<b>Form PTO-1449</b> (modified)		Atty. Docket No. OSTS:003USD2/SLH	Serial No. 09/879,445
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Gregory R. Mundy Wolfgang E. Gallwitz	
		Filing Date: June 11, 2001	Group: Unknown
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	



### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C17	Suda N, Gillespie MT, Traianedes K, Zhou H, Ho PWM, Hards DK, Allan EH, Martin TJ, Moseley JM. Expression of parathyroid hormone-related protein in cells of osteoblast lineage. <i>J Cell Physiology</i> 166:96-104, 1996.
	C18	<i>The Merck Index</i> , no. 22, XP-002068023, Budavari, ed., 1996, Merck Research Laboratories, Whitehouse Station, NJ, USA.
	C19	<i>The Merck Index</i> , p. 1593, XP-002068022, Budavari, ed., 1996, Merck Research Laboratories, Whitehouse Station, NJ, USA.
	C20	Vargas SJ, Gillespie MT, Powell GJ, Southby J, Danks JA, Moseley JM, Martin TJ. Localization of parathyroid hormone-related protein mRNA expression in breast cancer and metastatic lesions by in situ hybridization. <i>J Bone Min Res</i> 7: 971-979, 1992.
	C21	Vickery BH, Avnur Z, Cheng Y, Chiou SS, Leaffer D, Caufield JP, Kimmel DB, Ho T, Krstenansky JL. RS-66271, a c-terminally substituted analog of human parathyroid hormone-related protein (1-34), increases trabecular and cortical bone in ovariectomized, osteopenic rats. <i>J Bone Min Res</i> 11:1943-1951, 1996.
	C22	Vortkamp A, Lee K, Lanske B, Segre GV, Kronenberg HM, Tabin CJ. Regulation of rate of cartilage differentiation by indian hedgehog and pth-related protein. <i>Science</i> 273:613-622, 1996.
	C23	Wysolmerski JJ, Vasavada R, Foley J, Weir EC, Burtis WJ, Kukreja SC, Guise TA, Broadus AE, Phillipbrick WM. Transactivation of the PTH-rP gene in squamous carcinomas predicts the occurrence of hypercalcemia in athymic mice. <i>Cancer Res</i> 56: 1043-104, 1996.
	C24	Yin JJ, Taylor SD, Yoneda T, Dallas M, Boyce BF, Kumagai Y, Mundy GR, Guise TA. Evidence that parathyroid hormone-related protein (PTH-rP) causes osteolytic metastases without hypercalcemia. <i>J Bone Min Res</i> 10 (Suppl 1) #122, 1995.
	C25	Yu <i>et al.</i> , "Vitamin D analogs: new therapeutic agents for the treatment of squamous cancer and its associated hypercalcemia", <i>Anti-Cancer Drugs</i> , 6:101-108, 1995.

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Information Disclosure Statement — PTO-1449 (Modified)

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